

endoprosthetic vertebral body 320, and a screw 362 can be turned into the anchor 352 so as to rigidly assemble the leg 342 to a leg 354 extending from the lower endoprosthetic disc unit 318.

In an alternate embodiment, ear 340 could be replaced with a biodegradable washer around each of the screws 92, 94 at a point located between the strap 250 and the respective leg 72, 74. (FIG. 10.) The washer could be of a size to overlaid and fix in place the interlocking wing leg from the adjacent intervertebral disc space. Alternately, ear 340 (FIG. 8.) may be eliminated in favor of screws 92, 94 having a head of increased diameter so that the screw head engages and fixes both the slotted leg 72, 74 and the interlocking tongue leg.

The upper disc endoprosthesis 308, the endoprosthetic vertebral body 320, and the lower disc endoprosthesis 318 can all be assembled and interconnected as a unit before implantation in a patient's body when indicated.

As also suggested in FIG. 6, the annular corners 372, 374 of natural vertebral bodies 312, 314 each can extend irregularly radially outwardly of the adjacent disc endoprosthesis 308, 318. However, the corners 382B, 384B of the prosthetic vertebral body 320 do not generally extend significantly outside those disc units 308, 318, thus discouraging vertebral body engagement with and consequent abrasion or other damage to adjacent portions of the patient's natural anatomy. Preferably the endoprosthetic vertebral body 320 is not exactly right cylindrical in shape, but is rather slightly biconical; that is, the endoprosthetic vertebral body 320 has a waist 390 of minimum radius R at an axial medial point as suggested in FIG. 6.

According to yet another aspect of the invention, novel surgical procedures permit effective and permanent installation of the endoprosthetic vertebral body 320 and associated parts. First, a surgeon or medical technician develops information about the size, shape and nature of a patient's damaged vertebral body or bodies from radiographs, CT and/or MRI scans, noting specifically the anterior-posterior and lateral dimensions of the end plate of each involved vertebral body and the vertical height of the anterior aspect of each involved vertebral and/or proximate vertebral body and vertical height of the mid portion of involved and proximate relatively normal intervertebral disc spaces. This information is transmitted by telephone, computer datalink or documentary transport to a specialized laboratory. That laboratory constructs one or more prosthetic assemblies of the sort shown in FIG. 6 in conformity with the received information and this disclosure. Each of the assemblies can include a prosthetic vertebral body 321, and at each body end is a prosthetic disc 308, 318. Each prosthetic disc unit comprises, in turn, the concaval-convex elements 30; the resilient body 20 interposed between the concaval-convex elements; and the seal unit 110 secured around the interior legs and resilient body. Thereafter, the completed and conformed assembly is implanted in the patient's spine 10.

When the unit or units have been received and the patient properly prepared, the damaged natural spinal disc or discs and vertebral body or bodies are removed and the adjacent spinal bone surfaces are milled or otherwise formed to provide concave surfaces to receive the confronting convex surfaces 52, 54. Thereafter, the disc units and vertebral body are installed in the patient's spine.

To accurately locate the concaval-convex surfaces in the patient's spine, holes 382A, 384A (FIG. 3) are precisely located and then formed in the bone structure using a measuring instrument centered in the evacuated natural

intravertebral disc space. These holes are then tapped to form female threads therein. When the threads have been formed, the anchors 102, 104 are implanted in the respective tapped holes, thereby creating an imaginary platform of reference points located precisely with respect to the patient's spine. After the holes have been formed and the anchors 102, 104 implanted, a bone surface milling jig (not shown) is affixed to the anchors 102, 104 and the desired concave surfaces of predetermined shape are formed on the inferior and superior surfaces of the opposing vertebral bodies using one of a selection of predetermined milling head or bit sizes. Thereafter, the bone milling jig is removed and the concaval-convex elements 52, 54 identical in shape to the milled surfaces 112, 114 are inserted between the distracted milled vertebral bodies 12, 14. The distraction device is then moved. The concaval-convex structures are then attached by the same anchors 102, 104 to the bone, thus insuring a precise and stable mate between the bone surfaces and the convex surfaces 52, 54.

If necessary, a damaged implanted nucleus and/or gasket 24 can be removed and replaced. This can be accomplished by slitting the seal 110; removing the annular gasket 24 and damaged nucleus 22, and replacing them with new, undamaged elements. Thereafter, the seal 110 can be re-established by suturing or gluing closed the slit seal.

We claim:

1. A vertebral disc endoprosthesis, comprising a resilient body formed of materials varying in stiffness from a relatively stiff exterior portion to a relatively supple central portion; and concaval-convex elements at least partly surrounding the resilient body for retaining said resilient body in a position between the concaval-convex elements, and wherein said concaval-convex elements each comprise generally L-shaped supports, each support having a first concaval-convex leg, the first leg having an outer convex surface for engaging adjacent bone and a corresponding inner concave surface for retaining the resilient body, each support further having a second leg extending generally perpendicularly to the first leg and adapted for affixation to adjacent bone structure.

2. A vertebral disc endoprosthesis according to claim 1 wherein said resilient body comprises an annular gasket and a nuclear central portion.

3. A vertebral disc endoprosthesis according to claim 2 wherein the gasket extends about the nuclear central portion to enclose it within a thin layer.

4. A vertebral disc endoprosthesis according to claim 3 wherein the gasket, the nuclear central portion, and the thin layer are molded together as one piece.

5. A vertebral disc endoprosthesis according to claim 1 further comprising cannulated screw means for attaching the concaval-convex element supports to adjacent bone structure.

6. A vertebral disc endoprosthesis according to claim 5 wherein said cannulated screw means comprises a screw, and a screw anchor seatable within bone structure and adapted to threadably receive the screw.

7. A vertebral disc endoprosthesis according to claim 6 wherein the screws terminate in the anchor.

8. A vertebral disc endoprosthesis according to claim 6 wherein the anchor has an open end and the screw proceeds through the open end of the anchor and terminates in the bone of the vertebral body.

9. A vertebral disc endoprosthesis according to claim 1 further comprising a seal member attached to the concaval-convex elements and surrounding said resilient body.

10. A vertebral disc endoprosthesis according to claim 9 wherein said seal member comprises a flexible sheet mate-

rial having a multiplicity of pores, the pores being from about 5 microns to about 60 microns in size.

11. A vertebral disc endoprosthesis according to claim 10 further including sealing means applied to said flexible sheet material to render said flexible sheet material substantially impervious to the passage of any fluid.

12. A vertebral disc endoprosthesis according to claim 11 wherein the sealing means is silicone.

13. A vertebral disc endoprosthesis according to claim 9 wherein said concaval-convex elements and said seal member collectively surround said resilient body with a watertight seal.

14. A vertebral disc endoprosthesis according to claim 2 wherein said annular gasket is relatively stiff and said nuclear central portion is relatively supple.

15. A vertebral disc endoprosthesis according to claim 1 wherein at least one of the second legs is hingedly attached to the respective first concaval-convex leg.

16. A vertebral disc endoprosthesis, comprising a resilient body formed of materials varying in stiffness from a relatively stiff exterior portion to a relatively supple central portion; and concaval-convex elements at least partly surrounding the resilient body between adjacent vertebral bodies for retaining the resilient body between adjacent vertebral bodies in a patient's spine, and wherein said concaval-convex elements each comprise generally L-shaped supports, each support having a first concaval-convex leg, the first leg having an outer convex surface for engaging adjacent bone and a corresponding inner concave surface for retaining the resilient body, each support further having a second leg extending generally perpendicularly to the first leg and adapted for affixation to adjacent bone structure, wherein at least the second leg is constructed of titanium.

17. A vertebral disc endoprosthesis comprising a resilient nucleus, first and second rigid concaval-convex elements at

least partly surrounding the nucleus, first and second legs formed, respectively, with the first and second rigid concaval-convex elements, first and second means for affixing the respective legs to vertebral bodies adjacent the concaval-convex elements and nucleus, longitudinal ligament prosthesis means extending between the legs of the first and second concaval-convex elements to inhibit undesirable motion of the vertebral bodies relative to one another, and biodegradable washers positioned between the ligament prosthesis means and the respective legs.

18. A vertebral disc endoprosthesis comprising a rounded, resilient nucleus body convex on all surfaces and concaval-convex elements, each concaval-convex element being of relatively constant cross-sectional thickness and having an outer convex surface for engaging adjacent bone structure which has been milled to mate with the concaval-convex element outer convex surface, and a corresponding inner concave surface for engaging the rounded resilient body, wherein lubricant is provided between the nucleus body and the concaval-convex elements.

19. A vertebral endoprosthesis comprising an integral disc unit, said unit including a pair of confronting L-shaped supports having concaval-convex shapes in given legs, a resilient body interposed between the supports, and a flexible seal extending from one support to the other and sealing the resilient body within the supports inside a substantially watertight compartment, further comprising a plurality of said integral disc units.

20. The vertebral disc endoprosthesis according to claim 19 wherein each support includes a groove about its circumference.

\* \* \* \* \*